Major Kidney Clinical Research Studies and Projects Inventory*

Folic Acid for Vascular Outcome Reduction in Transplantation (FAVORIT)

1. Administrative Data

(a) Name of study/research project and acronym:

Folic Acid for Vascular Outcome Reduction in Transplantation (FAVORIT), A Randomized Controlled Clinical Trial of the Effect of a High Dose Combination of Folic Acid, Vitamin B6, and Vitamin B12, on Arteriosclerotic Cardiovascular Disease Outcomes in Chronic, Stable Renal Transplant Recipients

(b) Type of study/research project (randomized clinical trial, epidemiological study, database, etc.):

Randomized clinical trial

(c) Funding status (currently funded, study/project completed):

Currently funded

(d) Recruitment status (recruitment completed, currently recruiting):

Currently recruiting

(e) For studies/projects currently recruiting: indicate total sample size/ number currently enrolled, anticipated period of recruitment:

Total sample size = 4,000; currently enrolled (as of data retrieval 1/8/03) = 252; recruitment 2/1/02-1/30/04

(f) Data coordinating center principal investigator contact information (mailing address, phone, fax, e-mail address):

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(g) Number of recruiting sites, list of principal investigators at recruiting sites, and contact information as in (f) above:

20 recruiting sites. See Appendix A.

(h) List of principal investigators at central laboratories/facilities (identify type of central facility) and contact information as in (f) and (g) above:

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Jean Mayer USDA Human Nutrition Research Center on Aging
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(i) Roster of Data and Safety Monitoring Board/Scientific Advisory Committee or other oversight committee(s):

Janet Whittes, Charles Herzog, Peter W.F. Wilson, Robert Phillips, Rex Jamison (see Dr. John Kusek for complete list)

(j) Private-sector support (type of support, e.g., financial, donation of drugs/placebo, etc.):

Pamlab LLC is contributing the multivitamins. SangStat, Amgen, and Roche Pharmaceutical each made a financial donation for plastic bags with the FAVORIT logo.

2. Study Design (for completed studies, a copy of the primary publication can substitute for information below)

(a) Objective:

To determine whether total homocysteine (tHcy)-lowering treatment with a standard multivitamin augmented by a high dose combination of folic acid, vitamin B12, and vitamin B6 reduces the pooled rate of recurrent and denovo cardiovascular disease outcomes among clinically stable renal transplant recipients who have mild to moderately elevated tHcy levels.

(b) Study design:

Twenty large academic renal transplant centers across the United States and Canada will participate, each contributing approximately 200 patients for a total of 4,000 randomized participants. After screening, eligible participants will be randomized into one of the two treatment groups and be followed at yearly clinic visits and through semi-annual telephone visits until death or a maximum of five years.

(c) Major inclusion criteria:

- Chronic, clinically stable renal graft function 6 months post transplantation
- Cockcroft-Gault serum creatinine estimate of >= 30mL/min
- tHcy level >=12.0 umol/L for men, or >=11.0 umol/L for women
- Abstain from B6, B12 and folic acids for 4 weeks before screening
- Age 35-75 years at time of randomization
- Adequate cognitive function
- Geographically accessible
- Informed consent
- Adequate transportation

(d) Major exclusion criteria:

- Presence of cancer, end-stage congestive heart failure, liver or pulmonary disease, progressive HIV or other chronic wasting illness which would limit life expectancy to less that two years
- Pregnant or lactating women or women of childbearing potential not practicing birth control
- Participating in another clinical trial specifically involving CVD risk factor management
- Inability to be randomized with 120 days of screening

- Less than 3-months post acute myocardial infarction, or stroke, or less than 3-months post coronary artery, renal artery or lower extremity artery PTCA, or lower extremity amputation

- Less than 6-months post coronary artery bypass graft surgery, abdominal aortic aneurysm repair surgery, or carotid endarterectomy

(e) Description of the intervention(s):

Eligible subjects will be randomized in a double blind manner to one or two treatment groups: multivitamins containing a high dose combination of folic acid, vitamin B6, and vitamin B12, or an identical multivitamin containing no folic acid, and Estimated Average Requirement (EAR) amounts of vitamin B6 and vitamin B12.

(f) Baseline/eligibility visit schedule (number of visits, major assessments):

The baseline/randomization visit includes informed consent; medical history and detailed current medication review; intake of folic acid, vitamin B6, and vitamin B12 from supplement; basic physical activity data collection; and random blood collection for tHcy, folate, vitamin B12, pyridoxal 5'-phosphate (PLP), lipid profile, creatinine and glucose determinations. The randomization visit should coincide with the patients' regularly scheduled renal clinic visits.

(g) Follow-up contact schedule (frequency, type of visit/phone, in-clinic, major assessments):

Follow-up clinic visits every 12 months include general medical histories focusing on hospitalizations, emergency room, and physician's office visits; full medication inventories; intake of folic acid, vitamin B12 and vitamin B6 from supplements; pill counts; and blood tests. Telephone follow-up at 6-month intervals includes questions regarding hospitalizations, outpatient or physician visits, study medication compliance, and pill counts.

(h) Primary outcome, secondary outcomes:

Primary outcomes are recurrent or *de novo* arteriosclerotic cardiovascular disease (CVD) defined as the occurrence of non-fatal or fatal arteriosclerotic outcomes, including coronary heart, cerebrovascular and peripheral vascular disease events (myocardial infarction, resuscitated sudden death, coronary artery revascularization, stroke, and requirement for an invasive procedure for peripheral or renovascular disease).

(i) Brief summary of power estimates used to justify sample size/duration, including critical assumptions (i.e., effect-size estimates, estimated event rates or rate of change in outcome measure):

Random sample surveys of the 20 proposed FAVORIT centers revealed that ~35% of those renal transplant recipients meeting basic eligibility criteria (i.e., with respect to age, time since renal transplantation, and current creatinine clearance) were diabetic (i.e., currently undergoing treatment with insulin or oral anti-diabetic medications). Power calculations used the USRDS diabetic stratum-specific CVD rate, applied to a projected FAVORIT population whose prevalence of diabetes at randomization would be 35%. Based on the tHcy screening eligibility criterion, our published treatment data (Beaulieu AJ, Gohh RY, Han H, Hakas D, Jacques PF, Selhub J, Bostom AG. Enhanced reduction of fasting total homocysteine levels with supraphysiological versus standard multivitamin dose folic acid supplementation in renal transplant recipients. *Arterioscler Thromb Vasc Biol* 1999;19: 2918-2921.) and the prospective data of Ducloux et al (Ducloux D, Motte G, Challier B, Gibey R, Chalopin J-M. Serum total homocysteine and cardiovascular disease occurrence in chronic, stable renal transplant recipients: a prospective study. *J Amer Soc Nephrol* 2000; 11:134-137.), the active treatment will reduce tHcy levels by a mean of ~6 μmol/L, which *could* translate into a reduction in the CVD event rate of ~35-40%.

However, we have made the following conservative final estimates, based on the germane USRDS sample event rates (above) for both the pooled CVD outcome of interest, and the development of dialysis-dependent ESRD: *With a sample size of 4000, and with 5% of each treatment group assumed to take no vitamins, and 5% of each group assumed to instead take a standard ove-the-counter vitamin preparation, power is calculated to be 83.0% to detect a 19% treatment effect, and 87% to detect a 20% treatment effect, i.e., either a 19.0% or 20.0% reduction in their pooled CVD event rate, for those assigned to the multivitamin containing high doses of folic acid and vitamins B6 and B12.*

The study is designed to recruit 4,000 patients (2,000 in each group) over a 2-year period for 83%-87% power to detect a 19.0% to 20.0% treatment effect during 5 years of follow-up.

(j) Web site:

The FAVORIT website can be accessed at http://www.cscc.unc.edu/favorit/

3. Data and Biological Sample Resources

(a) Biological samples collected in ongoing studies/research projects (specify the type of sample, e.g., blood, urine, etc., the amount, and the point in the study when samples were

collected, e.g., baseline visit #1, baseline visit #2, follow-up visit #1; specify months after randomization/study entry):

See tables below.

3(a). Sample Processing Schedule: Screening Visit

Specimen/ Container Type	#	Test Request	Aliquot Volume	Aliquot Code	Storage Instructions	Special Instructions
EDTA Plasma/ 5 mL Lavender Top Vacutainer	1	Total Homocysteine (tHcy) Plasma Archive Buffy Coat (WBC's) RBC Archive	1000 µL 1000 µL ~500 µL 1000 µL	LT1 LT2 LT3 LT4	Wkly Ship Hold Hold Hold	Foil/Wet Ice **See ****
Serum/5 mL Marble Top Vacutainer	1	Creatinine Glucose Serum Archive	750 µL 750 µL 1000 µL	MT1 MT2 MT3	Wkly Ship Hold Hold	

3(a). Sample Processing Schedule: Randomization and Follow-Up Months 12, 24, 36, 48, and 60

Specimen/ Container Type	#	Test Request	Aliquot Volume	Aliquot Code	Storage Instructions	Special Instructions
EDTA Plasma/ 10 mL Lavender Top Vacutainer	1	Total Homocysteine (tHcy) B12/folate PLP Plasma Archive-1 Buffy Coat (WBC's) RBC Archive-1 RBC Archive-2	500 µL 1000µL 500 µL 1000 µL ~500 µL 1000µL 1000µL	LT1 LT2 LT3 LT4 LT5 LT6 LT7	–80°C	Foil/Wet Ice **See ****
EDTA Plasma/ 10 mL Lavender Top Vacutainer	1	Lipid Profile: Chol/Trig HDL LDL Plasma Archive-2	 500µL 500µL 500µL 1000µL	 LT8 LT9 LT10 LT11	–80°C	Foil/Wet Ice **See ****
Serum/10 mL Marble Top Vacutainer	1	Creatinine Glucose Fructosamine Serum Archive –1 Serum Archive - 2	500 µL 500 µL 500 µL 1000 µL 1000 µL	MT1 MT2 MT3 MT4 MT5	–80°C	
Sodium Citrate Plasma/4 mL Light Blue Top Vacutainer	1	Plasma Archive –1 Plasma Archive - 2	1000 µL Remainder	BT1 BT2	–80°C	Foil/Wet Ice **See ****
Urine/5 oz. Sterile Midstream Urine Collection Container	1	Creatinine Micro Albumin Urine Archive	1500 µL 1500 µL 1500 µL	UR1 UR2 UR3	–80°C	

(b) Biological samples currently in storage from completed trials (grid showing sample collection time, type of sample, amount, and number of study participants sample was collected from, and physical location of where the samples are stored):

N/A (trial in progress)

(c) Brief summary of typical informed consent provisions (template informed consent form acceptable), including major variables in participant consents, if applicable (for example, "use for other studies or not", "allow genetic studies or not.") Does consent include use of samples in other studies that are not part of the main study?

See attached Appendix B and C (Informed Consents)

(d) Data collected (grid of data collection by time/clinic visit with specificity on the type of information collected, e.g., quality of life with SF-MOS 36, measurement of kidney function by GFR, serum creatinine measurement, etc.):

See grid below.

3(d). Data Collection Schedule

Procedure (Months)	RC Eligibility	SC Base-Line/ Random-ization 0	P 6	SC/ RC 12	P 18	SC/ RC 24	P 30	SC/ RC 36	P 42	SC/ RC 48	P 54	SC/ RC 60
(Prior) Chart Review	X											
Random tHcy & creatinine	X											
Random bloods for tHcy, folate/B12, PLP, Lipid profile, creatinine, glucose, fructosamine, & archiving		X		X		X		X		X		X
Clinic Exam & Medical History		X		X		X		X		X		X
Medical History (abbreviated)			X		X		X		X		X	
Medication Inventory		X		X		X		X		X		X
Focused Adverse Reactions Survey			X	X	X	X	X	X	X	X	X	X
Focused Surveys: a) Intake of supplemental folic acid, vit. B6, & vit. B12 b) Physical Activity		X X	X	X X	X	X X	X	X X	X	X X	X	X X
Pill count			X	X	X	X	X	X	X	X	X	X

(e) Any provisions for distributing resources outside of the study? What is the sharing plan?

Through ancillary studies approved by the FAVORIT Executive Committee and IRB of institution originating proposal.

4. Ancillary Studies

(a) Process and contact person (name, address, phone, fax, and e-mail address) for application to perform ancillary studies:

Ancillary study proposals are submitted to the FAVORIT Executive Committee c/o Andrew Bostom, MD, Principal Investigator, Rhode Island Hospital, Renal Division, POB 242, 593 Eddy St., Providence RI 02903; *Phone:* 401-444-6460; fax 401-444-2217; *E-mail*: abostom@lifespan.org

(b) List of ancillary studies approved, completed, and ongoing (including source of funding and amount):

None approved, ongoing, or completed at this writing. Two studies are under review.

5. List of Publications and Presentations (full citations, also note manuscripts in progress)

"Coordinating Center Experience with 'Just-In-Time' Start-Up of a Multinational Randomized Controlled Clinical Trial"; Myra A. Carpenter, Hope Bryan, James D. Hosking, and the FAVORIT Study Group; *The University of North Carolina* Chapel Hill, NC; abstract submitted to the Society for Clinical Trials.

***Cooperative Agreement, Contract, and Selected Investigator-Initiated, NIDDK-Supported Studies**

Appendix A. Recruiting Site Principal Investigators

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Appendix A

Appendix B. FAVORIT Consent Form: Participation in Trial

_____
Study Volunteer Initials

Affiliate

☐ Rhode Island Hospital ☐ VNA of Rhode Island

☐ The Miriam Hospital

☐ Bradley Hospital ☐ Newport Hospital

Agreement to Participate in a Research Study

_____ _____
Committee # Name of Study Volunteer

Folic Acid for Vascular Outcome Reduction In Transplantation

You are being asked to take part in a research study. All research studies carried out at Lifespan institutions are covered by rules of the Federal government as well as rules of the State and Lifespan institutions. Under these rules, the researcher will first explain the study, and then he or she will ask you to participate. You will be asked to sign this agreement which states that the study has been explained, that your questions have been answered, and that you agree to participate.

The researcher will explain the purpose of the study. He or she will explain how the study will be carried out and what you will be expected to do. The researcher will also explain the possible risks and possible benefits of being in the study. You should ask the researcher any questions you have about any of these things before you decide whether you wish to take part in the study. This process is called informed consent.

This form also explains the research study. Please read the form and talk to the researcher about any questions you may have. Then, if you decide to be in the study, please sign and date this form in front of the person who explained the study to you. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study

Patients with chronic kidney disease have a high risk of developing arteriosclerotic and cardiovascular disease and related complications (like angina, heart attack, poor circulation and stroke). This increased risk may be due in part to a higher level of homocysteine in their blood. It is unknown whether treatment to lower total homocysteine levels will reduce the chance of these complications among patients with chronic kidney disease.

This study will compare 4000 people from 20 transplant centers in the United States and Canada. 2000 people will take multivitamins with high dose combinations of folic acid, B6, and B12 and 2000 people will take multivitamins with no folic acid and Estimated Average Requirement amounts of vitamin B6 and B12. Their medical history will be followed for 5 years to evaluate whether or not treatment with a high dose combination of folic acid, vitamin B6, and Vitamin B12 will reduce the complications of arteriosclerotic cardiovascular disease.

The sponsor of the study is the National Institutes of Health

2. Explanation of Procedures

Your participation in this study is voluntary. Your physician has examined your medical and laboratory records. You have stopped taking any multivitamins for 4 weeks prior to the initial visit. At that visit approximately 1 tablespoon of blood will be drawn and tested for homocysteine and creatinine levels, and occasionally an extra tube will be drawn for laboratory quality control purposes.

If you qualify for the study, you will return to the clinic in approximately 3 weeks for a randomization visit (approximately 30 minutes). At this visit, you will have physical measurements, blood pressure and history and approximately 2-3 tablespoons of blood and a urine sample will be taken and be tested for levels of homocysteine, vitamins and creatinine; occasionally an extra tube of blood or extra urine sample will be taken for laboratory quality control purposes. You will randomly (by chance) be assigned to receive multivitamins containing a high dose combination of folic acid, vitamin B6, and vitamin B12, or an identical multivitamin containing no folic acid, and Estimated Average Requirement amounts of vitamin B6 and vitamin B12. Your chance of receiving either drug is 50/50. Neither you nor the study personnel will know which drug you are taking, however, this information is available in case of emergency.

We will record your name, address, telephone number, social security number, and United Network for Organ Sharing (UNOS) or Canadian equivalent number to help enable us to keep in contact with you throughout the study. We may also use this

information to link with the National Death Index, the UNOS database or the United States Renal Data System (or Canadian equivalent) so we have more complete information on your risks for cardiovascular and kidney diseases and your health outcomes. This personal identifying information will be used for no purposes other than those listed above. Otherwise it will be held in strict confidence by the FAVORIT study personnel or by the National Institutes of Health (the study sponsors) throughout the study and following the study completion. Information about you that is published or otherwise released will be combined with information about other patients in the study in such a way that your individual information cannot be determined.

We will ask you to sign a Release of Medical Information form so that we can find out details of any medical problems, particularly any heart or vascular problems, for which you receive your care from doctors other than those at the Rhode Island Hospital/Lifespan We will also ask you to allow us to contact your family members or other individuals you've identified if you die or cannot be contacted by FAVORIT staff throughout the end of the study.
You will have your regularly scheduled, yearly clinic visits with your transplant doctor for a physical, history, medication review and blood and urine samples (approximately 30 minutes). A small portion of the blood and urine collected will be stored for future testing related only to the risk for cardiac and kidney disease.

You will have a telephone "visit" every 6 months for a short medical history, pill count and reporting of any adverse events (approximately 15 minutes).

You will bring all your bottles of study medication (used and unused) to your yearly clinic appointments for a pill count and at your completion of the study you will return all bottles (used and unused). The duration of the study is 5 years during which you will visit your doctor approximately 7 times, and have telephone "visits" 5 times at prescheduled dates
There are no additional costs to you. All study medication will be provided to you at your clinic visits in childproof containers.

If you have questions or concerns during your participation in this study, you may contact Dr. Andrew Bostom at 401-444-6460 or Dr. Reginald Gohh at 401-444-8562.

3. Discomforts and Risks

Study participants will be monitored for reports of possible side effects from vitamin supplements, which may include itching, rash, nausea and vomiting.

Risks associated with drawing blood from your arm include pain, bruising, lightheadedness and, on rare occasions, infection.

4. Benefits

You may or may not benefit from participating in this study. There is little risk but there may be some benefit if the administration of a high dose vitamin supplement proves to be helpful in reducing the risk of arteriosclerotic and cardiovascular disease events in chronic, stable renal transplant recipients.

5. Alternative Therapies

If you decide not to participate, or withdraw after entering the study, the post transplant care you would normally receive will be provided. Women who become pregnant during the study will not be excluded for receiving the usual multivitamins that are prescribed during pregnancy.

6. Confidentiality

All of your records from this study will be treated as confidential medical records. The records will be safeguarded according to the policy of the Lifespan institution. This policy is based on Rhode Island law, which promotes protection of confidential health care information. State law requires health care providers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires health care providers to report abuse or neglect of persons age 60 and older to the Department of Elderly Affairs.

While the results of the research study will probably be shared with other people and may be published in scientific reports, your name and the fact that you were in the study will be kept confidential.

Information from this study may be available to representatives of the Food and Drug Administration (FDA), The National Institutes of Health and the Committee on Clinical Investigations at Rhode Island Hospital which oversees all clinical trials.

7. Refusal/Withdrawal

The decision whether to be in this study is entirely up to you. Participation is voluntary. Also, if you decide now to participate, you will be able to change your mind later and withdraw from the study.

There will be no penalty or loss of health care benefits if you decide not to participate, or if you withdraw from the study. If the researcher or your doctor feels it is in your best

interest, they may choose to end your participation in this study at any time prior to the completion of the study.

The researcher will provide you with additional information, as it becomes available, that may affect your decision to continue in the research study.

In addition, the sponsor may choose to end the study at any time
for reasons unrelated to health care.

8. Medical Treatment/Payment in Case of Injury

We do not expect any unusual risk in this research study. If an unexpected injury occurs as a result of your participation in this study, Lifespan will provide you with what it considers fair and appropriate treatment for that injury, without charge to you. Lifespan will not however, provide any money or other payment if this happens. Signing this consent does not reduce or revoke any of your legal rights. For more information regarding this provision, please contact Kathy Handshaw in the Office of Research Administration at 401-444-6246

9. Rights and Complaints

If you have any complaints about your participation in this study, or would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact Kathy Handshaw, anonymously if you wish, in the Lifespan Office of Research Administration, telephone number 401-444-6246.

_____
Study Volunteer Initials

I ACKNOWLEDGE THAT I HAVE READ THE ABOVE EXPLANATION OF THIS STUDY THAT ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY.

_____ _____
Signature of study volunteer/authorized representative* Date

I ACKNOWLEDGE THE PROCESS AND/OR SIGNATURE OR STATEMENT SET FORTH ABOVE

_____ _____
Signature of witness (required if consent is presented orally or at the request of the IRB) Date

I CERTIFY THAT I HAVE EXPLAINED FULLY TO THE ABOVE PATIENT THE NATURE AND PURPOSE, PROCEDURES AND THE POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS RESEARCH STUDY.

_____ _____
Signature of researcher or designate Date

Consent form copy: ☐ study volunteer ☐ medical record ☐ researcher ☐ other (specify)

*If signed by agent other than study volunteer, please explain below.

Appendix B

Appendix C. FAVORIT Consent Form for Specimen Banking

_____
Study Volunteer Initials

Affiliate

☒ Rhode Island Hospital ☐ VNA of Rhode Island

☐ The Miriam Hospital ☐ Hospice Care of R.I.

☐ Bradley Hospital ☐ Newport Hospital

FOLIC ACID FOR VASCULAR OUTCOME REDUCTION IN TRANSPLANTATION

I. AGREEMENT TO PARTICIPATE IN SPECIMEN BANKING

(IDENTIFIABLE SAMPLES)

Your doctor has asked you to participate in a study sponsored by the National Institutes of Health. As part of this study, blood and body fluid samples will be collected from you for the purposes of this study only.

It may be possible to do special research tests in the future if you agree to allow the specimen blood and body fluid samples you have donated to be saved after the study is finished. These future tests may bear no relationship to the present study; that is, they may be for different conditions or for different purposes. Your signature below will allow for a specimen to be stored in a central specimen bank, with the possibility that it may be used in future tests. These future tests may not directly benefit you, but may provide important medical knowledge. If you decide to donate your specimens for future testing, you will be given a copy of this consent form after you sign it. A copy will be kept in your study and/or medical records.

A. **Confidentiality and Privacy of Medical Record**

All stored specimens will be kept confidential. Access to the specimens will be limited to investigators and lab personnel. No other people, including relatives and personal doctor will have access to the stored samples, or information about them without your written consent. Appropriate physical and computer security measures will be maintained to limit access to specimens. Your specimens will be labeled in code rather than under your name.

Only your doctors and authorized researchers will be allowed to read records that

have your name on them. Papers or articles which are based on this study or on future studies will not identify you by name.

B. **Control and Ownership of the Specimens**

Once you have donated your specimens for placement in the specimen bank, you will have given up most of your rights with respect to owning the specimen. The researcher or specimen bank will be considered a "sequential owner" of the sample. Future researchers using the donated specimen for later studies will also become "sequential owners". For example, there is a very remote possibility that your specimen may become part of a process or product that ultimately has commercial value. However the rights to any profits from this commercial process or product would belong to the researcher who brought about the process or product. If you should have a need for the sample at some later date for a medical purpose, it usually can be removed for that purpose.

C. **Withdrawal of Your Consent**

If you decide at some time in the future that you no longer wish your stored specimen to be used in future studies, you may have the right to request that the specimen be withdrawn from the specimen bank. However, withdrawal cannot be guaranteed. It is possible that your specimen will have been used to create a new cell line and thus removal would be impossible. It is also possible that the specimen is no longer identifiable as belonging to you.

You may refuse to donate your specimens for future studies and still be able to participate in the current study.

D. **Length of Storage**

Specimens in the bank will be stored for an indefinite period of time, until research funding is exhausted or the specimen is no longer usable. The sample may also be used to create a transformed cell line, which will also be stored for an indefinite period of time.

E. **Future Access to Genetic Information**

Information may be learned for this study or from future studies using your donated specimens that may be medically important to you. Depending on the study, this information may be passed on to all study participants, including yourself.

This information may be upsetting or may make you uncomfortable. You have the right to choose whether or not to be told about this information. If you would prefer not to be informed of this information, researchers will respect that choice, except in rare cases where the researchers and genetic counselors feel morally

compelled to disclose the information to study participants. For example, researchers may learn of information important to your personal or family safety or to that of others, and in such a case, they are morally compelled to disclose that information to you. Such cases are rare.

Consent

I agree to donate my specimens to be kept in a central specimen bank for possible future research. I understand that the specimens maybe saved for an indefinite length of time and may be used in more than one future study.

I wish / do not wish (circle one) to be informed of any medical information which may be learned in future research studies using my donated specimen(s) and which may personally affect me or my family.

_____ _____

Participant Date

_____

Witness (only if consent presented orally)

_____ _____

Participant's legal representative Date
(If patient unable to sign)

Appendix C